

## **REMARKS**

### **Remarks Regarding Claim Amendments**

Claims 30, 31, 34-46 and 48-64 are currently under examination in the instant application of which claims 30 and 31 are independent. Claims 39-44 and 54-59 have been withdrawn. Claims 1-29, 32, 33, 47 and 62 have been canceled. Claims 30, 31, 48 and 49 have been amended and new claims 65-66 have been added.

Claim 30 has been amended to recite that the polymer cured in the mold forms a membrane comprising a surface with varying topology including at least one feature with at least one dimension of about 10 to 100 microns. Support for this amendment may be found throughout the specification such as, for example, in original claim 31 and in paragraph [0006].<sup>1</sup> Claim 31 has been amended to incorporate the limitations of claim 62, *i.e.*, that the microfabricated polymer scaffold comprises a plurality of membranes. Claim 31 has been further amended to recite that the membranes include at least one feature with at least one dimension of about 10 to 100 microns. Support for this amendment may be found throughout the specification such as, for example, in paragraph [0006]. Claims 30, 31, 48 and 49 have been further amended to place the claims in better form and to advance prosecution of this application.

Upon entry of these amendments, claims 30, 31, 34-46, 48-61 and 63-66 will be pending in the instant application. These amendments are fully supported and justified by the application as originally filed. No new matter has been added by these amendments and their entry is respectfully requested. Applicants reserve the right to pursue the subject matter of the unamended claims in one or more related applications.

### **Remarks regarding 35 U.S.C. § 112**

Claim 48 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, claim 48 is allegedly indefinite for reciting “a method” which does not further limit claim 30. Applicants have amended claim 48 as suggested by the Examiner by replacing “method” with “polymer scaffold.” Therefore, this rejection is now moot and Applicants respectfully request its withdrawal.

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<sup>1</sup> All references to Applicants' specification are to U.S. Pub. Appln. No. 2005/0008675 A1.

**Remarks regarding 35 U.S.C. § 102**

1. Claims 30, 34-36, 45, 46, 48 and 49 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Weiss *et al.* (U.S. 6,143,293, "Weiss"). Applicants respectfully traverse.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987). Conversely, if each and every element in a claim is not found in a single prior art reference, there can be no anticipation.

Weiss describes three dimensional scaffolds for tissue generation (*See, e.g.*, Abstract and col. 6, lines 2-5). The three dimensional scaffolds are generated "using mechanical fasteners, such as screws, sutures and microbarbs" to assemble sections or layers of scaffold material (col. 6, lines 2-5). Weiss exemplifies these three dimensional scaffolds using hydroxyapatite subsections 1 mm thick and 10 mm in diameter that were sewn together with nylon sutures (col. 11, line 41 - col. 12, line 24).

Amended independent claims 30 is directed to, *inter alia*, a microfabricated polymer scaffold comprising two or more polymer membranes that are layered to provide a scaffold, where a membrane comprises a surface with varying topology including at least one feature with at least one dimension of about 10 to 100 microns. Applicants respectfully assert that Weiss does not disclose a membrane comprising a surface with varying topology including at least one feature with at least one dimension of about 10 to 100 microns. Because Weiss does not teach these features, claim 30 cannot be anticipated by Weiss. Claims 34-36, 45, 46, 48 and 49, as well as newly added claim 65, incorporate the recitations of claim 30, and cannot be anticipated by Weiss for the same reason.

For the reasons stated above, Applicants assert that the pending claims are not anticipated by Weiss and respectfully request the withdrawal of this rejection.

2. Claims 31, 50, 60, 61 and 63 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Masini *et al.* (U.S. 2001/0043918, "Masini"). Applicants respectfully traverse.

Masini describes, *inter alia*, a system and methods for mechanical loading of a tissue engineered scaffold in culture (*See, e.g.*, Abstract and ¶¶ [0010] - [0012]).

Independent claim 31 has been amended, *inter alia*, to incorporate the limitations of

claim 62 (*i.e.*, that the microfabricated polymer scaffold comprises a plurality of membranes), which the Office Action does not allege to be anticipated by Masini. Because claim 31 incorporates the recitations of claim 62, claim 31 cannot be anticipated by Masini either. Claims 50, 60, 61 and 63, as well as newly added claim 66, incorporate the recitations of claim 31, and cannot be anticipated by Masini for the same reason.

Independent claim 31 has also been amended, *inter alia*, to recite that the membranes include at least one feature with at least one dimension of about 10 to 100 microns. Applicants respectfully assert that claim 31 is not anticipated by Masini for the additional, independent reason that Masini does not disclose a membrane that includes at least one feature with at least one dimension of about 10 to 100 microns. Because Masini does not teach these features, claim 31 cannot be anticipated by Masini. Claims 50, 60, 61 and 63, as well as newly added claim 66, incorporate the recitations of claim 31, and cannot be anticipated by Masini for the same reason.

For the reasons stated above, Applicants assert that the pending claims are not anticipated by Masini and respectfully request the withdrawal of this rejection.

**Remarks regarding 35 U.S.C. § 103**

3. Claims 37, 38 and 64 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Weiss in view of Ma (U.S. 6,872,387, "Ma"). Applicants respectfully traverse.

Ma describes, *inter alia*, the use of ionically crosslinked alginate gels as scaffolds for in vitro tissue engineering applications (*See, e.g.*, col. 2, lines 21-24 and col. 5, lines 50-54).

Dependent claims 37, 38 and 64 are directed to, *inter alia*, a microfabricated polymer scaffold comprising two or more hydrogel membranes that are layered to provide a scaffold. Further, claims 37, 38 and 64 depend on claim 30 which recites, *inter alia*, that a membrane comprises a surface with varying topology including at least one feature with at least one dimension of about 10 to 100 microns, and this recitation is incorporated into claims 37, 38 and 64 by nature of their dependency on claim 30.

The Office Action alleges that one of ordinary skill in the art would have been motivated to modify Weiss to incorporate the hydrogel polymer scaffolds of Ma to arrive at the invention of claims 37, 38 and 64.

As discussed above, Weiss does not teach or suggest a membrane comprising a surface with varying topology including at least one feature with at least one dimension of about 10 to

100 microns as recited in claim 30. The addition of Ma does not cure this defect of Weiss. As Ma describes hydrogel scaffolds of Ma with dimensions of millimeters and not microns (*See, e.g.,* col. 3, lines 10-16 and 53-55 and col. 6, lines 7-53), Applicants respectfully assert that Ma does not teach or suggest a membrane comprising a surface with varying topology including at least one feature with at least one dimension of about 10 to 100 microns as recited in claim 30, and the claims that depend therefrom. Since Weiss and Ma do not, individually or in combination, disclose a membrane comprising a surface with varying topology including at least one feature with at least one dimension of about 10 to 100 microns, they cannot render claims 37, 38 and 64 obvious.

Furthermore, claims 37, 38 and 64, are not obvious over Weiss in view of Ma for the additional, independent reason that, at the time of Applicants' invention, a person having ordinary skill in the relevant art would not have modified Weiss in view of Ma. At the time the invention was made, a person having ordinary skill in the relevant art would not have thought it feasible to layer or fuse thin hydrogel membranes. Thin hydrogels are weak and difficult to manipulate and layer, and as a result, it would have been considered impracticable to layer or fuse thin hydrogel membranes. Therefore, a person having ordinary skill in the relevant art would not have modified Weiss in view of Ma.

For at least the reasons stated above, Applicants respectfully assert that the pending claims, including claims 37, 38 and 64, are not obvious over Weiss in view of Ma. Applicants therefore respectfully request the withdrawal of this rejection.

4. Claims 51-53 and 64 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Masini in view of Ma. Applicants respectfully traverse.

Claims 51-53 depend on claim 31 which recites, *inter alia*, a microfabricated polymer scaffold comprising a plurality of membranes, each comprising a surface with varying topology including at least one feature with at least one dimension of about 10 to 100 microns, and this recitation is incorporated into claims 51-53 by nature of their dependency on claim 31. Claim 64 depends on claim 30 which recites, *inter alia*, membranes comprising a surface with varying topology including at least one feature with at least one dimension of about 10 to 100 microns, and this recitation is incorporated into claims 64 by nature of its dependency on claim 30. Dependent claims 51-53 and 64 are further directed to, *inter alia*, biopolymer or hydrogel

membranes.

The Office Action alleges that one of ordinary skill in the art would have been motivated to modify Masini to incorporate the hydrogel polymer scaffolds of Ma to arrive at the invention of claims 51-53 and 64.

As discussed above, Masini does not teach or suggest membranes that include at least one feature with at least one dimension of about 10 to 100 microns as recited in claim 31 [or claim 30]. The addition of Ma does not cure this defect of Masini. As Ma describes hydrogel scaffolds of Ma with dimensions of millimeters and not microns (*See, e.g.*, col. 3, lines 10-16 and 53-55 and col. 6, lines 7-53), Applicants respectfully assert that Ma does not teach or suggest a membrane that includes at least one feature with at least one dimension of about 10 to 100 microns as recited in claim 31, and the claims that depend therefrom. Since Masini and Ma do not, individually or in combination, disclose membranes that include at least one feature with at least one dimension of about 10 to 100 microns, they cannot render claims 51-53 and 64 obvious.

Furthermore, claims 51-53 and 64, are not obvious over Masini in view of Ma for the additional, independent reason that, at the time of Applicants' invention, a person having ordinary skill in the relevant art would not have modified Masini in view of Ma. At the time the invention was made, a person having ordinary skill in the relevant art would not have thought it feasible to layer or fuse thin hydrogel membranes. Thin hydrogels are weak and difficult to manipulate and layer, and as a result, it would have been considered impracticable to layer or fuse thin hydrogel membranes. Therefore, a person having ordinary skill in the relevant art would not have modified Masini in view of Ma.

For at least the reasons stated above, Applicants respectfully assert that the pending claims, including claims 51-53 and 64, are not obvious over Masini in view of Ma. Applicants therefore respectfully request the withdrawal of this rejection.

5. Claim 62 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Masini in view of Weiss. Applicants respectfully traverse. Claim 62 has been cancelled, therefore the rejection of claim 62 is moot.

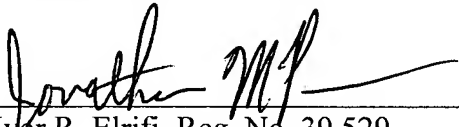
**CONCLUSION**

Favorable action on the merits is respectfully requested. If there are any questions regarding this Response, the Examiner is encouraged to contact the undersigned at the telephone number provided below to expedite further processing of the application.

Applicant believes no additional fees are due with the filing of this Response. However, if any additional fees are required or if any funds are due, the USPTO is authorized to charge or credit Deposit Account Number: **50-0311**, Customer Number: **35437**, Reference No.: **36796-502C01US**.

Respectfully submitted,

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